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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/614,072 | 07/02/2003 | Steven D. Goodman | 89188.0046 | 6624 |
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| HOGAN & HARTSON L.L.P. 500 S. GRAND AVENUE SUITE 1900 LOS ANGELES, CA 90071-2611 | | | EXAMINER TONGUE, LAKIA J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1645 | |

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/614,072

Applicant(s)

GOODMAN ET AL.

Examiner

Lakia J. Tongue

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 23-25 is/are pending in the application.
4a) Of the above claim(s) 7-13 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-6, 14-20, 23-25 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

1. Applicant's response filed on August 22, 2005 is acknowledged. Claims 1-6, 14-20, 23-24 and newly added claim 25 are pending and under consideration. Claims 7-13 and 21-22 have been canceled and withdrawn from consideration. With respect to the above-mentioned response the examiner has withdrawn the finality of that action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Rejections Withdrawn

2. In view of applicant's response, the rejection over claims 14-17, 19 and 20 under 35 U.S.C. 102(e) on page 3, paragraph 5 is withdrawn.

3. In view of applicant's response, the rejection over claims 1-6 and 14-24 under 35 U.S.C. 112, first paragraph on page 5, paragraph 6 is withdrawn.

4. In view of applicant's response, the rejection over claims 1-6 and 14-24 under 35 U.S.C. 102(e) on page 9, paragraph 7 is withdrawn.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-6, 14-20 and 23-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition and a medicament for the treatment of attachment of *S. mutans* to teeth comprising an isolated Competence Stimulating Peptide (CSP), wherein the CSP comprises SEQ ID NO: 1, wherein the composition is capable of inhibiting attachment of *S. mutans* to teeth, does not reasonably provide enablement for a composition or a medicament comprising an isolated Competence Stimulating Peptide (CSP) and sucrose for the prophylaxis of any condition associated with the attachment of *S. mutans* to teeth or a condition which is selected from dental caries or endocarditis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to a composition comprising an isolated Competence Stimulating Peptide (CSP) and sucrose, wherein the CSP comprises SEQ ID NO: 1, wherein the composition is capable of inhibiting attachment of *S. mutans* to teeth.

Dental caries continues to pose an important health problem worldwide. Idone et al (Effect of an orphan response regulator on *Streptococcus mutans* sucrose-dependent

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adherence and cariogenesis, *Infection and Immunity*, 2003; 71(8): 4351-4360) teaches that the sucrose-dependent adherence of *S. mutans* to teeth ensures that bacteria will not be washed away with chewing or the flow of saliva thereby increasing its ability to adhere to the tooth surface (page 4351).

Sucrose is the most common form of added sugar in the diet. Zero teaches that sucrose has been given special importance due to its involvement as the sole substrate in the synthesis of extracellular glucans mediated by microbial glycosyltransferases. When compared to other dietary sugars (glucose, fructose and lactose) in the rat caries model, sucrose has been shown to be more cariogenic. It was suggested that replacement of sucrose by monosaccharide reduces proximal and smooth surface caries. The studies show that sucrose-mediated synthesis of glucans increase the porosity of plaque, permitting deeper penetration of dietary sugar into the biofilm and greater acid production immediately adjacent to the tooth surface (Zero, Sugars- The arch Criminal?, *Caries Research*, 2004; 38: 277-285).

Moreover, Clark et al (Influence of salivary components and extracellular polysaccharide synthesis from sucrose on the attachment of *streptococcus mutans* 6715 to hydroxyapatite surfaces, *Infection and Immunity*, 1977; 18(2): 514-523) studies the adsorption of *streptococcus mutans* to hydroxyapatite surfaces. The study showed that substituting glucose for sucrose in the diet results in a reduction in the proportions of *s. mutans* attachment (page 514).

Keys (Infective Endocarditis, The Cleveland Clinic, 2004; 1-12) teach that there is a continued debate about the need for and adequacy of antibiotic prophylaxis to prevent

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infective endocarditis (page 9). Moreover, Keys teach that penicillin, often in combination with gentamicin, remain cornerstones for therapy of endocarditis when due to susceptible streptococci (page 6).

In addition, the specification does not provide substantive evidence that the claimed composition is capable of inducing protective immunity. This demonstration is required for the skilled artisan to be able to use the claimed composition for their intended purpose of prophylaxis of a condition associated with the attachment of *S. mutans*, dental caries or endocarditis. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed composition, i.e. would not be able to accurately predict if protective immunity has been induced.

Factors to be considered in determining whether a disclosure would require undue experimentation have been reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CRFC1988). The Wands factors to be considered are:

- a. the quantity of experimentation necessary,
- b. the amount of direction or guidance presented,
- c. the presence or absence of working examples;
- d. the nature of the invention;
- e. the state of the prior art;
- f. the relative skill of those in the art;
- g. the predictability or unpredictability of the art;
- h. breadth of the claims.

The presence or absence of working examples utilizing the administration of an isolated Competence Stimulating Peptide (CSP) and sucrose, wherein the CSP comprises SEQ ID NO: 1 are exemplified in the instant specification, however it appears that the sucrose had no role in inhibiting attachment as suggested or that the above mentioned composition actually prevented any condition associated with the attachment of *S. mutans* to teeth, dental caries or endocarditis. The examples do not display a form of prevention. The examples only exhibit inhibition of *S. mutans* to teeth. There are no instances where an anti-caries agent was present in the composition thereby helping with the prevention of *S. mutans* attachment, dental caries or endocarditis. In fact Example 7 only exhibits a composition with CSP and sucrose present. The quantity of experimentation necessary would be undue for the utilization of any amount of CSP. The specification lacks guidance with respect to the utilization of CSP. The amount of direction or guidance presented is minimum in terms of working examples. The results of the putative treatment regimens exemplified in the examples are unclear. The specification only shows smooth surface inhibition. There was no reasonable material similar to tooth enamel. It is taught that hydroxyapatite mimics tooth enamel, the instant specification teaches the use of a Petri dish. Would plastic produce the same effect? According to Figure 8 the more sucrose present in the composition the more attachment was exhibited. When there was no sucrose and only CSP in the composition there was very little attachment exhibited and when there was sucrose and CSP present the CSP did not inhibit attachment. When there was sucrose and no CSP in the composition there was a great deal of attachment. What

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amount of CSP was used in each composition? What non-pathogenic organisms will or will not adhere to the teeth? The nature of the invention involves treatment or prophylaxis of any condition associated with the attachment of *S. mutans*, and without any specific guidance to the contrary, could result in damage to the patient. The art cites specific examples of why one would not want to use sucrose for the inhibition of *S. mutans* to teeth. In studies using an intracaries model, *Streptococcus mutans* plaque prepared from sucrose containing cultures were found to have markedly enhanced demineralization potential compared with glucose grown plaque (Zero, page 282). The relative skill in the art is recognized as high, the breadth of the claims is broad not only to include attachment of *S. mutans* to teeth, but also dental caries and endocarditis.

In view of all of the above, in view of the lack of predictability in the art, it is determined that it would require undue experimentation to make and use the claimed invention commensurate in scope with the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2, 3, 6, 15, 17 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The above-mentioned claims recite anti-caries agent, histidine-rich polypeptides and non-immunogenic amino acid segments of proline-rich proteins. The examiner is unclear what applicant intends by

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these recitations. What are the anti-carries agent, histidine-rich polypeptides and non-immunogenic amino acid segments of proline-rich proteins?

Conclusion


7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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